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DEPARTMENT OF NUCLEAR SAFETY
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March 2, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Ln, Rm 1061
Rockville, MD 20852

REF: Federal Register Vol. 64, No. 235, December 8, 1999
pp 68696-68697 Docket No 99D-4910

Dear Sir:

The Illinois Department of Nuclear Safety hereby submits its comments on the above identified Draft Compliance Guidance: The Mammography Quality Standards Act (MQSA) Final Regulations Document # 3. This guidance document is intended to assist facilities in implementing the requirements of MQSA.

Personnel - General (21CFR900.12(a))

The guidance for individuals that do not meet the requirements of this section is vague with regard to whether the individuals may continue to perform their duties while in noncompliance. While we would agree that a person who does not meet the initial requirements may present a risk to the overall quality of mammography performed at the facility, we do not believe such a risk is present when the facility is simply lacking documentation or when an individual has not completed the required amount of continuing education.

Equipment - Application of Compression (21CFR900.12(b)(8)(i))

For machines such as the GE 500T, which requires tapping the foot pedal for fine adjustment of the compression force, we suggest that FDA simply note that these machines comply with the requirement. After all, when FDA proposed this rule and did its cost analysis, who assumed that these units would not comply with the new standard? Why is this now an issue?

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Equipment - Technique Factor Selection and Display (21CFR900.12(b)(9))

The guidance for these requirements should also note that it applies to the display of focal spot selection.

Mammographic Image Identification (21CFR900.12(c)(3))

The requirements of this rule list seven items which must appear on the mammographic image. FDA should recognize that many facilities may be surprised as to the extent of this requirement, perhaps because it is not presently a component of the inspection process.

Mammographic Equipment Evaluations (21CFR900.12(e)(10)

This requirement remains one of the most confusing of the final regulations, and as we have seen in previous communications, FDA is not offering any guidance that is particularly helpful. We continue to await FDA's explanation as to what type of repairs or component replacements will or will not necessitate involvement of the physicist.

We appreciate the opportunity to comment on this issue.

Sincerely,

Paul H. Brown, Chief
Division of Electronic Products

PHB:wda

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